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**Sacral neuromodulation: standardized tined lead implantation technique:
two-year clinical outcome and sensory response upon lead stimulation
comparing the use of the curved versus straight stylet**

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Abstract: **OBJECTIVES** To assess clinical follow-up data over 24 months using the standardized tined lead implantation technique, comparing the use of the curved vs straight stylet. **PATIENTS AND METHODS** Single tertiary center, prospective study (August 2013 - June 2015) involving 40 patients with overactive bladder and 15 with non-obstructive urinary retention refractory to first-line treatment. **PRIMARY OUTCOME** successful tined lead procedure; intention to treat analysis at 12 and 24 months. Secondary outcome: number of optimal electrode configurations during programming. Statistical analysis was performed by plain non-parametric tests for numeric and categorical data. **RESULTS** 33/35 (94%) patients implanted with the curved stylet had a successful tined lead procedure versus 13/20 (65%) implanted with the straight stylet ($p=0.005$). Intention to treat analysis at 12 and 24 months was 94% and 91% for the patients with the curved stylet compared to 65% and 45% for those with the straight stylet ($p=0.002$ and $p<0.001$). 60% and 25% of the electrode configurations in the curved group were considered optimal and bad in comparison to 40% and 37% in the straight group ($p<0.001$). The main limitation is the non-randomized study design. **CONCLUSIONS** The use of the standardized implantation technique with the curved stylet leads to more successful tined lead procedures, better success rates after 2-years follow-up and more optimal electrode configurations when compared to use of the straight stylet placement. This article is protected by copyright. All rights reserved.

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Sacral neuromodulation: standardized timed lead implantation technique: two-year clinical outcome and sensory response upon lead stimulation comparing the use of the curved versus straight stylet

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Curved vs. straight stylet

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Keywords: sacral neuromodulation, sacral neurostimulation, pelvic organ dysfunction, overactive bladder, urinary retention, urinary incontinence

Abstract

Objectives: To assess clinical follow-up data over 24 months using the standardized tined lead implantation technique, comparing the use of the curved vs straight stylet.

Patients and methods: Single tertiary center, prospective study (August 2013 - June 2015) involving 40 patients with overactive bladder and 15 with non-obstructive urinary retention refractory to first-line treatment. Primary outcome: successful tined lead procedure; intention to treat analysis at 12 and 24 months. Secondary outcome: number of optimal electrode configurations during programming. Statistical analysis was performed by plain non-parametric tests for numeric and categorical data.

Results: 33/35 (94%) patients implanted with the curved stylet had a successful tined lead procedure versus 13/20 (65%) implanted with the straight stylet ($p=0.005$). Intention to treat analysis at 12 and 24 months was 94% and 91% for the patients with the curved stylet compared to 65% and 45% for those with the straight stylet ($p=0.002$ and $p<0.001$). 60% and 25% of the electrode configurations in the curved group were considered optimal and bad in comparison to 40% and 37% in the straight group ($p<0.001$). The main limitation is the non-randomized study design.

Conclusions: The use of the standardized implantation technique with the curved stylet leads to more successful tined lead procedures, better success rates after 2-years follow-up and more optimal electrode configurations when compared to use of the straight stylet placement.

Introduction

In the field of urology, sacral neuromodulation (SNM) is a well-accepted, minimally invasive treatment for patients with overactive bladder dry (OABD) or wet (OABW), and for patients with non-obstructive urinary retention (NOUR), refractory to conservative treatments (1). A tined lead with 4 stimulation electrodes is placed through the third or fourth sacral foramen and stimulates sacral spinal nerves in its vicinity. Since the sacral spinal nerves are mixed nerves, it is currently still

unknown which nerve fibers are stimulated (autonomic vs somatic, afferent vs efferent) and what the mechanism of action is for specific conditions being treated with SNM (2).

Success rates after 2-3y of follow-up (FU) reported by well-designed multicenter prospective studies vary from 50 to 76% on a “per protocol analysis” (PP) (3-6). Unfortunately, there is a lack of clarity in true “intention to treat” (ITT) results from those studies, incorporating all patients that were screened with the SNM tests. Based upon the provided study data and the percutaneous needle examinations and tined lead test results, intention to treat results would be around 27-61% (3-6). The reason for these variable and suboptimal success rates are unknown but could be related to patient selection or lead placement.

Recently, a European panel of high volume implanters described a standardized tined lead implantation technique based upon live operating sessions with concomitant discussions, including all recently published modifications of the technique (7). The aim of the standardized technique was to reduce the variability in lead placement linked to the surgeon and/or the patient and to improve lead implantation resulting in lower activation thresholds and to improve the efficacy rates. This paper recommends the use of the curved stylet, as it is more flexible and may enable a more parallel position of the lead to the target sacral spinal nerve. Theoretically this should result in an increasing number of active electrode poles providing a higher likelihood for optimal effect and lower stimulation intensity.

The primary aim of the current paper is to assess the effect of the curved vs straight stylet on long term clinical outcome using the standardized tined lead implantation technique. The secondary aim is to assess the effect of the curved vs straight stylet on the sensory response upon lead stimulation.

Material and methods

Between August 2013 and June 2015 patients eligible for SNM were screened for inclusion in this prospective observational study. Patients with OABD and OABW, refractory to at least two different antimuscarinics were eligible, as were patients with NOUR who were on clean intermittent catheterization. Patients with known neurological diseases or low back surgery were excluded. From August 2013 till March 2014, 20 patients were implanted using the straight stylet, whereas from April 2014 till June 2015, upon the description by Jacobs et al. (8) on the use of a curved stylet suggesting better outcomes, 35 consecutive patients were implanted using the curved stylet.

Implant procedure

In both groups the standardized tined lead placement technique recently described in detail (7)) was used, with the only difference being a curved vs straight stylet inside the lead upon introduction. The procedural key points are: 1) ideal patient position aiming to remove the lumbar lordosis. 2) Skin marking of the medial edges of the foramina X-ray guided by anteroposterior (AP) view, followed by skin marking of the line through the lower edges of the sacroiliac joint. The intersection points of the lines mark at the bony level, the upper medial part of the third sacral foramen, the ideal site for lead entry. 3) Inserting the needle and testing for the proper response, which is characterized by an inward movement of the bellows upon stimulation (14 Hz – 210 μ s) with amplitudes < 2mA. If this response was not obtained, the needle was removed and reintroduced in the same foramen and tested again. If after 3 needle reintroductions in the same foramen the optimal response was not found, another foramen was tested. In this study, the S3 left was probed first for response, followed by S3 right, S4 left and S4 right if no adequate answer was obtained. 4) Placing the dilator while making sure the tip did not protrude beyond the inner table of the sacrum, X-ray guided by lateral view. 5) Placing the tined lead with the use of the straight or curved stylet. Final position was determined by achieving a clinical response with a current stimulation of <2mA giving inward movement of the bellow for as much electrodes as possible. With the use of the curved stylet, rotation of the tip allowed for small adjustments in the lateral and AP deflection of the lead. Patients were tested with an external pulse generator for 3 weeks. Success upon the test was defined as >50% improvement in relevant parameters noted on a 3-days bladder diary. For patients with OABW, incontinence and urgency episodes were evaluated, for patients with OABD, 24hour frequency and for NOUR reduction in post void residual determined by intermittent catheterization. Success after 12 and 24 months was defined by asking patients if they were satisfied with the treatment, using a verbal analogue scale ranging from 0-100% (cutoff for satisfaction \geq 80%), and if they wished to receive add-on treatment or alternative treatments. Patients indicating that they were satisfied and did not wish add-on or alternative treatments were considered a success and were additionally asked to fill in a 3-days bladder diary to associate their perception of treatment with the bladder diary. Patients not satisfied or requesting add-on or alternative treatments were considered failures. Outside the evaluation intervals during follow up (12 and 24 months), patients could contact a dedicated physiotherapist in case of reduced or lack of efficacy. At those events, the implantable pulse generator (IPG) was read out with the clinically used N-Vision and other electrode configurations were programmed. Pulse duration and frequency were fixed at 210 μ s and 14 Hz and were not changed throughout the study.

After the pulse generator was implanted, a “sensory passport” was determined for each patient. All the different electrode configurations were tested, the amplitude of the perception threshold was noted and the patients marked the location of the perceived sensation upon stimulation on a dermatome chart of the perineum. The different locations were then coded as perianal, genital or other (leg, toe, buttock, lower back). To determine the perception thresholds, the method of limits was used, 4 mA was the upper limit. If no sensation was reported at 4 mA, this configuration was noted as “not perceived”, since these high thresholds jeopardize battery longevity.

Currently, it is not known whether the sensation upon stimulation in a specific location is associated with higher success in individual patients. However, patients with perianal and genital sensations less often experience uncomfortable stimulation (9), are less likely to require reprogramming (10) and generally tend to do better (11), in comparison to patients with sensations down the leg or buttocks. Therefore, perianal and genital sensation were considered prognostically good, whereas “other” or “not perceived” were considered bad.

Statistical analyses

All numerical data are presented as mean with standard deviation. Categorical data are presented as a percentage. Treatment success rates are given both on PP and ITT. Statistical significance testing was performed using Mann-Whitney U test (MWU) or Friedman test with post-hoc analysis using Wilcoxon signed rank test for numerical variables, and chi-square test for categorical variables. All analyses were done using IBM SPSS Statistics 23®. All statistical tests were two-tailed and were conducted with type I error probability of 0.05.

Ethical approval

This study was approved by the committee for Medical Ethics UZA-UAntwerp (14/50/526).

Results

Outcome

The study population consisted of 42 female (76%) and 13 male (24%) patients. Mean age was 51.7 +/- 17.0 years (range 18-79 years); 6 patients had OABD (11%); 34 OABW (62%) and 15 NOUR (27%). Baseline frequency in OABD was 16.5 +/- 3.6 voids/24h; baseline urgency incontinence in OABW was 4.4 +/- 2.7 episodes/24h. All patients with NOUR were on aseptic intermittent self-catheterization 3-5x/24h. There was no difference in age (MWU; $p=0.82$), sex (χ^2 ; $p=0.67$), indication (χ^2 ; $p=0.67$) or baseline frequency and incontinence (MWHU; $p>0.23$) between the curved and straight group.

At the end of the test phase, success rates were significantly higher in the curved group, i.e. 94% in the curved vs 65% in the straight group (χ^2 ; $p=0.005$) (table 1). These patients received an IPG and were followed up. At 12 and 24 months, success rates were significantly higher in the curved vs straight group (χ^2 ; $p=0.002$) (table1). At 24 months, success in the curved group was 91% on ITT analysis compared to 45% in the straight group (χ^2 ; $p<0.001$) (table1). Subjective success at 12 and 24 months (being satisfied and not requesting additional/alternative treatment) was well associated with the changes in the bladder diary data. Table 2 illustrates the data from the bladder diaries from OABW patients reporting success at 24 months, showing maintenance of the therapeutic effect.

Tined lead implantation (placement)

The tined lead was placed in S3 left in 37%, S3 right in 44%, S4 left in 13% and S4 right in 6%. The foraminal level (S3 vs S4) or the side (left or right) was not related to outcome (χ^2 ; $p=0.70$). The mean amplitude of the sensory threshold was not different between the straight (1.9 ± 1.2 mA) and curved group (1.8 ± 1.0 mA) (MWU; $p=0.826$). The monopolar configurations had significantly lower sensory thresholds than its corresponding bipolar configurations (Friedman test, Wilcoxon signed rank test; $p<0.01$). The full data are shown in table 3. The location where the different electrode configurations were perceived was different between both groups (χ^2 ; $p=0.003$). In the curved group 53% of the configurations were perceived at the anus, compared to 40% in the straight group. Genital sensation was reported by 23% in both the curved and straight group. However, in the curved group only 19% was perceived at the “other” location (leg, toe, buttock, lower back), compared to 31% in the straight group.

From a clinical perspective, the most ideal stimulation would be perceived at the perianal or genital region with a stimulation amplitude <2 mA; suboptimal would be perianal or genital perception and stimulation amplitude ≥ 2 mA but ≤ 4 mA; bad stimulation would be >4 mA or perception at “other” locations. Comparing these clinical relevant parameters showed significant differences in favour of the curved group (χ^2 ; $p<0.001$). The data are presented in table 4.

During SNM treatment, patients may experience episodes of reduced/lack of efficacy, which can be solved by troubleshooting. The first step is changing the electrode configurations, assuming the patient has several “optimal configurations”. Table 5 lists the percentage of patients broken down in relation to the number of possible “optimal configurations” and shows that more patients with a curved lead have more backup configurations. The table indirectly also shows that 38% in the straight group and 15% in the curved group have less than 4 optimal configurations.

Discussion

SNM is a well-accepted, minimally invasive treatment for patients with OABD, OABW and NOUR refractory to conservative treatments (1). A lead with 4 stimulation electrodes is placed through the third or fourth sacral foramen and stimulates sacral spinal nerves in its vicinity. Initially, the test stimulation procedure involved insertion of a needle and temporary lead (insulated wired) for a 3 to 7 days test period. If test stimulation was favorable the insulated wire was removed, and a new lead was placed in the sacral foramen under direct vision, after surgically opening the sacral area. Since the lead which was placed during the test period differed from the lead used when implanting the IPG, efficacy rates are reported as PP. The latter, making comparison with other treatments for patients with OABD, OABW and NOUR, reporting efficacy rates as ITT, more difficult. In 2002, a percutaneous approach was described using a self-anchoring tined lead. This allowed for a less invasive lead implantation technique as well as maintaining the lead used in the test procedure when placing the definitive IPG.

Despite this technical improvement efficacy rates have remained similar, although good comparisons are hampered by how the results are reported. ITT results of well-designed multicenter prospective studies vary between 27 to 61% for the different placement techniques (3-6) .

Recently, a standardized tined lead implantation technique was described aiming to reduce the variability in lead placement linked to the surgeon and/or the patient and to improve lead placements to the target nerve, which however is currently still unknown, resulting in lower activation thresholds and improved efficacy rates (7). The data presented here are the first reporting on the efficacy using the standardized technique in the field of urology. Using the standardized tined lead placement technique with the curved and straight stylet, our study shows an ITT of 91 and 45%, respectively. The straight stylet data are in line with published data (3-6, 12-14), but the curved stylet data are clearly higher than previously described. Since patient screening was the same throughout the study, patient selection seems unlikely to explain the differences. Furthermore, the demographic characteristics of this study are in line with those previously reported, although our patients seem a little bit younger.

The higher efficacy rates presented in this manuscript with the curved stylet are most probably related to the implant technique and the curved design of the lead, making small adjustments in lead placement possible. Only one study also reported efficacy rates around 90% (15). Although the authors addressed patient selection as the main reason for this success, they probed the foramina up to 4 times, to be sure to obtain an optimal response upon needle placement. This systematic procedure for the tined lead implantation is similar to what is reported in the current study and may explain the similar success rates.

Our results show no difference in outcome between S3 and S4. A similar observation was found in a study reporting on the outcome of SNM for faecal incontinence (16). A lead is implanted in S4, instead of S3, when the best bellows response upon lead stimulation is elicited at this location. This could be explained by the fact sacral spinal nerves are mixed nerves and show a great variability in the functional distribution (17). Therefore, the foraminal level seems less important than the placement inside a foramen leading to an adequate bellows response upon stimulation. A randomized controlled trial comparing S3 vs S4 placement would be interesting to evaluate whether both placement in both levels are equivalent in clinical outcome.

In 2014 Jacobs et al. (8) published upon the use of a curved stylet inside the lead, making the lead curved and therefore more controllable to direct its position. They showed that the lead placement with the curved stylet was superior to with the straight one in terms of motor thresholds to evoke a motor response upon stimulation and the number of electrodes per patients that evoked such responses (8). They suggested that the use of the curved stylet could lead to more optimal lead positions, lower stimulation thresholds thus extending battery life and more programming options, potentially improving efficacy rates. Based upon the publication by Jacobs et al. (8), the curved stylet technique was introduced in our center. The hypothesis underlying the use of the curved stylet is that the straight stylet may not adequately follow the curvilinear course of the sacral spinal nerves (which run medial to lateral along the fascia of the piriformis muscle anterolateral to the sacrum) and may result in placement of the deeper electrodes further from the targeted nerve spinal nerve—resulting in higher energy needs. The curved stylet, however, may be directionally guided and it is probably less likely to penetrate the fascia around nerves and vessels, thereby aiding to achieve a natural lateral course lead during placement. Increased efficacy rates after 2 years for the curved (ITT 91%) vs the straight (ITT 45%) stylet in our study are in line with this hypothesis. Furthermore, if the lead placed with the curved stylet aligns better with the sacral nerve, more electrode configurations would lead to optimal sensory responses upon lead stimulation. To assess

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this, a sensory passport was developed which consists of the sensory threshold and the location where the stimulation was felt by the patient (perianal/genital/other) for each electrode configuration. The sensory threshold is thought to reflect the distance between the stimulating lead electrodes and sacral spinal nerve whereas the location where the stimulation is felt reflects the sacral spinal nerve which is being stimulated. Based on these two parameters, optimal (perianal/genital <2mA), suboptimal (perianal/genital ≥ 2 and ≤ 4 mA) and bad (>4 mA or “other”) electrode configurations were defined. Interestingly, when we solely compare the sensory threshold between the curved and straight group, no difference is found.

The use of the curved stylet has shown to lead to lower motor response thresholds and more active electrodes upon stimulation during lead placement (8). Moreover, the motor response is highly correlated with the sensory response (18) and Gilleran et al. (19) reported a higher number of active electrodes during lead placement lead to lower sensory thresholds during the first programming session. All these facts assume a lower sensory threshold for the curved stylet. However, our results did not show a significant difference in sensory threshold between those implanted with curved vs straight stylet. As our study did not aim to determine the motor threshold or number of active lead electrodes during lead placement, no estimation of the proximity of the lead to the nerve can be made based upon motor response. This study focused on the sensory response after lead implantation. Since no difference was found for sensory threshold, we postulate both leads are in proximity of the sacral spinal nerves but the lead with the curved stylet targets more somatosensory nerve fibers corresponding with the perianal dermatomes and the straight stylet more often stimulates somatosensory nerve fibers corresponding with the dermatomes of the leg, toe, buttock or lower back.

Therefore, when we also take into account the location of sensation, significantly more optimal configurations were seen in the curved group compared to the straight, suggesting more electrodes follow the target nerve more closely. The use of such a passport can be a powerful tool to assess lead placement and serve as a base document for future programming sessions in case of loss of efficacy, as reprogramming of electrode configurations occurs frequently, with mean reported reprogramming rates being 1,4 to 2,8 a year (15, 19-21), and often solves clinical inefficacy and undesirable stimulation and thereby avoiding lead revision (22, 23). Since significantly higher efficacy rates were found in the curved compared to the straight group, an association between the number of optimal electrode configurations and clinical outcome may exist.

The main limitation of this study is the non-randomized design. It should be considered, however, that the study was originally designed as a prospective study using the standardized tined lead implantation technique with the straight stylet. During the recruitment phase of this study, better results have been published with the curved stylet so we decided to adapt our protocol using the curved instead of the straight stylet. Although there was no randomization but two sequential series, i.e. the first 20 patients underwent lead implantation with the straight stylet and the curved stylet was used in all remaining patients, the in- and exclusion criteria were identical for all patients and the implantations were performed by the same surgeon (SDW). Thus, the comparison between the outcomes with the curved vs straight stylet seems justified and the follow-up is fairly long with 24 months.

Another limitation is the definition of success after 12 and 24 months follow up. Patient reported outcomes are difficult to define resulting in a wide variety of instruments (24). Furthermore, it is shown there's a high association between patient reported outcome measures on quality of health and bladder diaries in overactive bladder patients (25). Therefore this study used, in addition to bladder diaries, a rather clinically oriented outcome of satisfaction with no request for alternative or add-on treatment defined as success. This in the authors opinion relates well with quality of life and compliance of treatment. Furthermore, success as defined using these criteria were well associated with the bladder diary data showing maintenance of the therapeutic effect.

Conclusions

This study provides two-year clinical data on the standardized tined lead implantation technique for SNM and compares a curved vs straight stylet placement. The group implanted with the curved stylet showed a significantly higher IPG implantation rate as well as long-term success rate. Furthermore, a sensory passport was defined showing significantly more optimal electrode configurations in the curved group compared to the straight group.

Conflicts of interest

Stefan De Wachter is a consultant for Medtronic and receives a research grant from Medtronic. All other authors report no conflicts of interest.

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Tables

Table 1: Outcome.

	Curved	Straight	P-value
N	35	20	
Successful test*	33 (94%)	13 (65%)	Chi ² ; p=0.005
Outcome 12 months after implantation of IPG	33 (PP:100%/ ITT:94%)	12 (PP:92% / ITT:65%)	Chi ² ; p=0.002
Outcome 24 months after implantation of IPG	32 (PP:97% / ITT: 91%)	9 (PP: 69% / ITT: 45%)	Chi ² ; p<0.001

* More than 50% improvement in complaints, leading to implantation of an IPG

Abbreviations: IPG: implantable pulse generator

Table 2: Number of incontinence episodes/ 24h in OABW with successful test.

	Curved	Straight
Baseline	4.1 +/- 3.1	4.5 +/- 1.9
End of test phase	1.0 +/- 1.5	0.8 +/- 0.8
12 months FU	0.9 +/- 1.4	0.5 +/- 0.5
24 months FU	1.1 +/- 1.5	0.7 +/- 0.5

Abbreviations: FU: follow up

Table 3: Mean sensory thresholds of different electrode configurations.

	Curved	Straight
Case + 0-	1.6 +/- 0.8	1.7 +/- 1.0
1+ 0-	2.1 +/- 1.1	2.4 +/- 1.1
2+ 0-	1.9 +/- 0.9	2.0 +/- 1.2
3+ 0-	1.9 +/- 1.0	2.2 +/- 1.2
Case + 1-	1.4 +/- 0.7	1.6 +/- 0.9
0+ 1-	2.1 +/- 1.1	2.0 +/- 1.1
2+ 1-	1.9 +/- 0.9	1.9 +/- 1.3
3+ 1-	1.8 +/- 0.8	2.2 +/- 1.3
Case + 2-	1.4 +/- 0.8	1.1 +/- 0.9
0+ 2-	1.8 +/- 0.9	1.9 +/- 1.1
1+ 2-	2.0 +/- 1.0	1.8 +/- 1.1
3+ 2-	2.0 +/- 1.2	1.9 +/- 1.3
Case+ 3-	1.2 +/- 0.5	1.5 +/- 1.1
0+ 3-	1.8 +/- 1.0	2.2 +/- 1.3
1+ 3-	1.8 +/- 0.9	2.0 +/- 1.2
2+ 3-	2.0 +/- 1.1	2.2 +/- 1.3

Table 4: Sensory passport: percentage of the possible electrode configurations considered optimal, suboptimal or bad.

electrode configurations	Curved	Straight
Optimal (perianal/genital <2mA)	59.7%	40.4%
Suboptimal (perianal/genital >=2 and <=4mA)	15.0%	22.6%
Bad (>4 mA or “other”)	25.4%	37.0%

Table 5: Sensory passport: percentage of patients that have numbers of optimal electrode configurations – cumulative percent.

optimal electrode configurations	Curved	Straight
≥ 12	39.4%	15.4%
≥ 8	69.73%	30.8%
≥ 4	84.8%	61.5%
< 4	100%	100%